REMARKS/ARGUMENTS

Following entry of the present amendments, claims 1, 7-10, and 21-29 are pending and under consideration. In the present amendment, Applicants have amended claims 1 and 23 as explained below, and have cancelled claims 30-41 without prejudice to or disclaimer of the subject matter recited therein. Applicants expressly reserve the right to pursue subject matter of those claims as well as previously cancelled claims 2-6 and 11-20 in one or more continuation and/or divisional applications at a future time.

As for support, Applicants have amended claim 1 to specify:

> wherein the leukemia is acute lymphocytic leukemia (ALL), acute myeloid leukemia (AML), or chronic myeloid leukemia (CML), and the pre-leukemia is myelodysplastic syndrome (MDS), and the aleukemic malignant blood disease is non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM).

Support for this amendment may be found in the specification. For example, at page 11, line 7, Applicants state:

> Any type of leukemia is encompassed in the present invention . . . and the examples include acute lymphocytic leukemia (hereinafter referred to as ALL), acute myeloid leukemia (hereinafter referred to as AML), [and] chronic myeloid leukemia (hereinafter referred to as CML). Any type of pre-leukemia is e[n]compassed in the present invention . . . and the examples include myelodysplastic syndrome (hereinafter referred to as MDS). Examples of aleukemic malignant blood diseases are lymphoma, myeloma and the like. Examples of lymphoma include . . . non-Hodgkin's lymphoma (hereinafter referred to as NHL) and the like. Examples of myeloma include multiple myeloma (hereinafter referred to as MM) and the like.

At page 57, final paragraph that continues onto page 58, Applicants state:

> The medians of the patients suffering acute myeloid leukemia (AML), acute lymphoid leukemia (ALL), chronic myeloid leukemia (CML), myelodysplastic syndrome (MDS), non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM) were significantly higher than those of [the] healthy individual group,

> demonstrating that measured SCGF values in these diseases had been significantly elevated (Fig. 7).

Additional support for this amendment can be found in Table 4 at page 57 and in Figure 7.

The amendment to claim 23 is merely a grammatical change to reflect typical claim language usage. Thus, these amendments find full support in the specifications and add no new matter.

I. Summary of Interview

Applicants thank the Examiner for the courtesies extended in a telephonic interview held on May 28, 2008, with Lynne Milliot, on behalf of Jean B. Fordis. Applicants wish only to note that Jennifer Davis did not participate and ask that the record reflect the participation of "Lynne Milliot, on behalf of Jean B. Fordis."

II. Objection to Claims 27 and 28 Under 35 U.S.C. 112, Second Paragraph.

The Office objected to claims 27 and 28 under 35 U.S.C. 112, second paragraph, as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention." Office Action at p. 2, item no. 3. Specifically, the Office considered that:

> ["]KM2142 and KM2804 and hybridoma FERM BP-7923 or FERM BP-7922" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct hybridomas or monoclonal antibod[ies].

The Office alleges that Applicants "should amend the claims to provide deposit accession number or other means of distinctly claiming the referenced antibody." Office Action at p. 2, item no. 3.

Applicants respectfully traverse and note that "FERM BP" is the accession number indicator for deposits made under IPOD/AIST in Japan. As set forth in the attached pages from the website, IPOD/AIST is one of the recognized International Depositary Authorities (IDAs)

under the Budapest Treaty, and it manages the deposited samples by "their FERM BP accession numbers." Thus, the references to the hybridomas in Claims 27, 28, and 29 by the identifiers FERM BP-7922, FERM BP-7923, and FERM BP-7924 do set forth a means of distinctly claiming the recited monoclonal antibodies KM2142, KM2804, and KM2945. Thus, Applicants respectfully request withdrawal of the rejection.

III. Objection to Claims 1, 7-10, and 21-41 Under 35 U.S.C. 112, First Paragraph.

The Office rejected claims 1, 7-10, and 21-42 under 35 U.S.C. 112, first paragraph. The Office states that the "specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation." *Id.*

Applicants note with appreciation the Office's recognition that "the specification describes the means of measuring the levels of SCGF in the serum of patient[s], and the statistically significant difference in the serum SCGF levels in patients with very specific diseases, i.e. ALL, AML, CML,[ ]MDS[,] NHL or MM compare[d] to healthy individuals." *Id.* Thus, Applicants have amended claim 1 to recite these specific diseases.

Claim 1 now states "wherein the leukemia is acute lymphocytic leukemia (ALL), acute myeloid leukemia (AML), or chronic myeloid leukemia (CML), and the pre-leukemia is myelodysplastic syndrome (MDS), and the aleukemic malignant blood disease is non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM)." Furthermore, claims 30-41 have been cancelled without prejudice or disclaimer; most of these claims are now incorporated into amended claim 1. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 7-10, and 21-30 under U.S.C. 112, first paragraph, as allegedly not being enabled.

IV. Rejection of Claims 27 and 28 Under 35 U.S.C. 112, First Paragraph.

The Office rejected claims 27 and 28 under 35 U.S.C. 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Office action at p. 4, item no. 6. Specifically, the Office states that:

> In claims 27 and 28 it is apparent that the monoclonal antibod[ies] KM2142 and KM2804 are required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

Office action at p. 4, item no. 7.

The Office notes that the "specification on page 21 indicates that said antibodies have been deposited with National Institute of Advanced Industrial Science and Technology, Ibaraki," and now seeks an indication of whether the hybridomas have been deposited under the Budapest Treaty. Office Action at p. 5, item no. 7.

As requested, Applicants now provide a declaration confirming the deposit of the hybridomas referred to in Claims 27, 28, and 29, which produce monoclonal antibodies KM2142, KM2804, and KM2945, respectively, in the Budapest Treaty-approved IPOD/AIST with accession numbers FERM BP-7922, FERM BP-7923, and FERM BP-7924, respectively. This declaration includes both the Japanese deposit receipts and their English translations under "Appendix B" (please note that there is no Appendix A). Also as requested, the declaration indicates that all restrictions on release of the deposits will be irrevocably and without restriction or condition released to the public upon issuance of the patent. Thus, claims 27-29 satisfy the requirement of 35 U.S.C. 112, first paragraph. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants respectfully request reconsideration of this application, withdrawal of all objections and rejections, and the timely allowance of pending claims 1, 7-10, and 21-29. In the event that the Office does not find the claims allowable, Applicants request that the Examiner contact the undersigned at (650) 849-6607 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Date: July 1, 2008

By: Jean B. Fordis

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International Patent Organism Depositary (IPOD)

What about IPOD
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- Acceptable cells and microoganisms
- Research topics and major publication of IPOD

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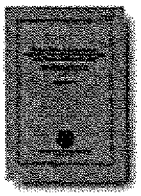
Mission of IPOD

Both as one of the depositaries which is designated by the Commissioner of the Japan Patent Office under the provisions of the Rule 27.2 of the Enforcement Regulations of the Patent Law, and as one of the International Depositary Authorities (IDAs) of the Budapest Treaty of the World Intellectual Property Organization (WIPO), IPOD receives and preserves cells/microorganisms relevant to the patent application and furnishes the cells/microorganisms on request to a third party/person who tries to test and/or study the invention in relation to them.



Budapest Treaty
on the International Recognition of the Deposit of Microorganisms the Purposes of Patent Procedure Regulation

Brief History of IPOD

IPOD has a long history. In 1968 the Fermentation Research Institute (FRI), that was attached to Agency of Industrial Science and Technology (AIST), started both receiving and furnishing the deposited microorganisms. FRI has been reorganized to National Institute of Bioscience and Human Technology (NIBH) in 1993, and to National Institute of Advanced Industrial Science and Technology (AIST) in 2001 to that IPOD attaches. Through the several institutional reorganization as above, and stepwise extension of biological varieties of the cells to be preserved, IPOD has continued receiving, preserving, and furnishing the cells/microorganisms deposited for patent application.

Holdings of IPOD

IPOD preserves around 14,000 samples being deposited for patent application, which includes microorganisms (fungi, yeasts, bacteria, actinomycetes) and plasmids, animal cell cultures and embryos, plant cell cultures, algae, protozoa, and seeds. All of these samples are managed by their FERM BP accession numbers.

Research of IPOD

IPOD is obliged to preserve the deposited cells/microorganisms alive at least for a certain term. In order that the skills for deposit, preservation, and furnishing of the

cells/microorganisms are advanced, IPOD is developing technologies for longtime preservation of cells, cellular phenotype and function, for simple identification of BSL2 microorganism and for detection of microbial contamination etc.

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